The association between a drop in systolic blood pressure from the individual reference value and in-hospital mortality in ED patients.

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A low delta SBP is associated with an increased risk of mortality

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27709

Bron
Nationaal Trial Register

Verkorte titel
DeltaSBP

Aandoening

Presentation in the ED

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: Maxima Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

in-hospital mortality

Toelichting onderzoek

Achtergrond van het onderzoek

Risk stratification of ED patients is important for appropriate initial treatment and disposition to a ward or intensive care unit (ICU). Clinical deterioration of patients often starts in the prehospital setting and only when patients start to feel too sick they will visit the GP or Emergency Department (ED). In a previous study we showed that the odds for in-hospital mortality increased approximately linearly with decreasing systolic blood pressure (SBP) starting at 140mmHg for unselected ED patients. Thus, on an average cohort level, prognosis of ED patients deteriorates already with SBPs below 140 mmHg. This may be explained by a relatively small number of ED patients who had a much higher SBP than 140 mmHg before they presented to the ED, as hypertension is a very common chronic disease in Western countries. If so, not only the initial SBP in the ED is relevant for prognosis but the absolute or relative reduction of the SBP which was normal for the individual patient before the ED presentation, i.e. it is important to know the baseline SBP of the individual patient. However, this information may often not be available in the ED as electronical patient records (EPR) are not routinely shared between general practitioners and hospitals in the Netherlands, due to privacy laws. In addition, in the outpatient clinics, blood pressure is not routinely measured. Before we can investigate the association between the absolute or relative reduction of SBP from the individual baseline SBP, we need to know in how many patients baseline SBPs are available. If indeed many baseline values are unavailable while the reduction of SBP is associated for the prognosis of the individual ED patient, this may plead for the need of a shared Electronic Patient Record (EPR) with the necessary clinical information, such as baseline vital signs. More importantly, if we find an association between a reduction of SBP from the individual baseline SBP and in-hospital mortality, a larger prospective cohort study would be indicated, which would than help to improve risk stratification of individual ED patients.
The aim of the present pilot study is therefore two-fold:
Objectives
1. To assess how often individual baseline values for SBP are known in ED patients.
2. To assess whether a change in SBP from the individual baseline values for SBP are associated with in-hospital mortality.

Doel van het onderzoek

A low delta SBP is associated with an increased risk of mortality

Onderzoeksopzet

We study overall in-hospital mortality or ICU admission from the ED. After discharge we don't follow-up on patients.

Onderzoeksproduct en/of interventie

no

Contactpersonen

Publiek

Leiden Universitair Medisch Centrum
Bart Candel

0644665616

Wetenschappelijk

Leiden Universitair Medisch Centrum
Bart Candel

0644665616

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients >70 years with ED visit and admission

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

triage category blue/green

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-11-2020
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	03-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9029
Ander register	METC Máxima MC : N20.052

Resultaten